AUG 1 2 2002

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3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

NewDeal SA
Parc d'Activitiés Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE

Telephone: (33) 4 74 78 15 15
Fax: (33) 4 74 78 15 16

B. ESTABLISHMENT REGISTRATION NUMBER: 9615741

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854

Tel: (301) 279 -2899
Fax: (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: April 11th, 2002

E. PROPRIETARY (TRADE) NAME: **HALLU®PLATES**

F. COMMON NAME: Metatarsal-phalangeal arthrodesis plate

G. CLASSIFICATION NAME AND REFERENCE

Plate, Fixation, Bone (21 CFR, Section 888. 3030)

H. PROPOSED REGULATORY CLASS: Class II

I. DEVICE PRODUCT CODE: 87 HRS

J. PANEL CODE: 87 OR Orthopedic

K. DESCRIPTION OF DEVICE:

The **HALLU®-PLATES** are available in two different designs :

- the **HALLU®-C PLATE**
- the **HALLU®-S PLATE**

The **HALLU®-C PLATE** and the **HALLU®-S PLATE** are low profile Titanium plates dedicated to first metatarso-phalangeal arthrodesis. Those implants are pre-bent for optimal anatomical adaptation (10° valgus and 10°dorsiflexion). Their fixation is provided by Titanium **SNAP-OFF®** screws available in a two diameters: 3.0 and 2.7 mm. They exist in different colors for size identification. The bone contact surface is sand blasted in order to maximize plate stability. The range of **HALLU®-C PLATE** and

HALLU®-S PLATE include 6 sizes (3left/3right) for optimal anatomic fit. Moreover, the **HALLU®-S PLATE** has an anatomical design providing optimal bone coverage.

L. INTENDED USE: The **HALLU®-PLATES** are intended to be implanted for fixation of fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint.

M. INDICATIONS FOR USE: The **HALLU®-PLATES** are intended to be implanted for fixation of fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint. Examples include:

-Hallux rigidus
-Severe hallux valgus (IM angle > 20° and HV angle > 40°)
-Deformity from rheumatoid arthritis
-Failed previous surgical procedure
-Traumatic arthritis
-Neuromuscular instability.

N. PREDICATE DEVICE: The **HALLU®- PLATES** are substantially equivalent to the **Howmedica** Luhr® plate (K935448) and **Howmedica** Profyle® Hand and Small Fragment System (K961497) , the **Acumed** Congruent bone plate system (K012655) and the **Synthes** modular foot system (K001941).

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The **HALLU®- PLATES**, the **Howmedica** Luhr® and **Howmedica** Profyle® plates, the **Acumed** plate and **Synthes** modular foot system are intended for internal bone fixation for bone fractures or reconstruction.

The **HALLU®- PLATES**, the **Howmedica** Luhr® and **Howmedica** Profyle® plates, the **Acumed** plate and **Synthes** modular foot system are all indicated for bone fractures or reconstruction in the foot.

The **HALLU®- PLATES**, the **Howmedica** Profyle® plates and the **Acumed** plate are in Titanium alloy TIAI6V4 whereas the **Synthes** modular foot system is manufactured in Stainless steel 316 L and the **Howmedica** Luhr® in Vitallium® alloy .

All those systems are fixed with screws except for the **Synthes** modular foot system attached to bone via buttress pins.

SUMMARY OF STUDIES:

Test 1 : Determination of bending strength and stiffness of bone plates was compared with requirement of the French Standard **ISO 9585** and **ASTM** standard **F-382-99** and found to have a bending stiffness and strength in compliance with the selected standards.

Test 2 : Determination of fatigue strength of bones plates were conducted and have shown the risk of rupture of the plate is minimal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NewDeal SA
c/o Norman F. Estrin, PhD, RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

AUG 1 2 2002

Re: K021626
Trade/Device Name: HALLU®-Plates System
Regulation Number: 21 CFR §888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: May 14, 2002
Received: May 17, 2002

Dear Dr. Estrin;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021626

Device Name: HALLU®-PLATES SYSTEM

Indications for Use:

The **HALLU®-PLATES** are intended to be implanted for fixation of fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint. Examples include:

-Hallux rigidus

-Severe hallux valgus (IM angle > 20° and HV angle > 40°)

-Deformity from rheumatoid arthritis

-Failed previous surgical procedure

-Traumatic arthritis

-Neuromuscular instability.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) OR Over-the-Counter Use

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021626

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